

## REMARKS

Reconsideration of this application is respectfully requested.

### A. Status of the Claims

Claims 1-40 and 47-49 have been cancelled. Claims 41 and 44 have been amended. The amendments to these claims are supported in the following representative passages of specification:

| <u>CLAIM</u> | <u>SUPPORT</u>  |
|--------------|---|
| 41           | Page 12, lines 15-16: "non replicative"<br><br>Page 25, line 6: "non infectious"<br><br>Page 3, lines 21-23: "lentiviral"<br><br>Page 7, lines 1-5 and Page 8, lines 1-4: "deprived of functional genes encoding lentiviral Gag, Pol, and Env proteins" |
| 44           | Page 3, lines 21-23 and original claim 8.   |
| 62           | Page 25, line 6   |
| 63           | Page 7, lines 22-24 and page 10, lines 3-9  |
| 64           | Page 3, lines 21-23 and original claim 8.   |
| 65           | Page 13, lines 15-17.   |

Claims 66-77 have also been added to the application. These claims are similar to claims 41-46, 50-51, and 62-65, except that claims 66-77 do not require that the cPPT and CTS sequence are "derived from a retrotransposon." (Compare claim 41, lines 5-10 with claim 66, lines 5-8.)

**B. Obviousness-type Double Patenting**

The Action indicates that the rejection for obviousness-type double patenting over U.S. Patent No. 6,682,907 is maintained until the Terminal Disclaimer filed on July 13, 2006, is granted. Applicant requests that the Terminal Disclaimer be granted and the rejection withdrawn.

The Action also indicates that the rejection for obviousness-type double patenting over U.S. Patent Application No. 10/313,038 is maintained until the Terminal Disclaimer filed on July 13, 2006, is granted. **Applicant notes that the Terminal Disclaimer filed July 13, 2006, does not make reference to Application No. 10/313,038.** However, because no claims have been allowed in either Application No. 10/313,038 or in this application, Applicant submits that the rejection should be held in abeyance at this time. Upon such time as claims in this application are allowed, Applicant will consider whether a Terminal Disclaimer is appropriate.

**C. Anticipation Under 35 U.S.C. § 102**

Applicant acknowledges with appreciation that the Examiner has withdrawn all prior rejections for anticipation.

**D. Obviousness Under 35 U.S.C. § 103**

Claims 41-51 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Verma et al. (WO 97/12622) ("Verma") in view of Charneau et al., 1994 ("Charneau '94") and Charneau et al., 1992 ("Charneau '92").

The Examiner summarizes Verma as “disclos[ing] a recombinant transfer vector comprising a transgene, encoding for luciferase or B-galactosidase, HIV-1 LTR and RRE, a packaging construct comprising HIV Gag, Pol, Vif, Tat, Rev and Nef, and a pseudotyping MLV vector comprising HIV Env.” Action at 4. The Examiner acknowledges that the Verma transfer vector does not comprise cPPT and CTS sequence. The Examiner then relies Charneau '94 for disclosure that cPPT is “an important cis-acting sequence for infectivity” and that “CTS is essential for HIV replication.” Action at 4. The Examiner also notes that Charneau '94 discloses a cPPT sequence and Charneau '92 a CTS sequence.

According to the Examiner:

[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Verma vector so as to include the cPPT and CTS as taught by Charneau '92 and Charneau '94. The skilled artisan would have been motivated to do so to improve the replication of the viral vector inside a cell and enhance the level of expression of the heterologous gene. There would have been a reasonable expectation of success, given the routine practice of molecular cloning in the art and the importance of cPPT and CTS for HIV replication, as taught by the two Charneau references.

Action at 5.

On that basis the Examiner concludes that “the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.” Action at 5. Applicant respectfully traverses the rejection.

The Office recently published Examination Guidelines to Determine Obviousness Under 35 U.S.C. § 103. Fed. Reg., Vol. 72, No. 195, October 10, 2007, at 57526

("Guidelines"). According to the Guidelines, in assessing obviousness an Examiner must first make findings of fact and then determine whether the claimed invention would have been obvious to one of ordinary skill in the art in view of those facts. Turning first to the necessary findings, an Examiner must (1) determine the scope and content of the prior art; (2) ascertain the differences between the claimed invention and the prior art; and (3) resolve the level of ordinary skill in the pertinent art. Then, in view of those findings the Examiner must articulate the reasons why the claimed invention would have been obvious in view of those facts. As the Guidelines emphasize, those reasons must be made explicit. Thus, mere conclusory statements are not sufficient; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. The Guidelines go on to present and discuss eight different rationales that may form a basis for a finding of obviousness. As Applicant will show, applying the procedure outlined in the Notice shows that the factual record does not support any of the rationales presented in the Notice. Therefore, the claims are not obvious over the cited references.

The Facts Developed by the Examiner

Applicant respectfully submits that the Examiner has not fully understood the deficiencies of the Verma reference. The Verma reference discloses a recombinant transfer vector. (See Figure 1, vector 2.) That vector does not include cis-acting sequences, cPPT and CTS, for formation of a DNA triplex, wherein the DNA triplex transfers the defined nucleotide sequence into the nucleus of a cell, as recited by the pending claims. That vector also does not include "regulatory signals for reverse

transcription, expression, and packaging,” as recited by the pending claims. Both of those features are recited in Applicant’s claims but absent from the transfer vector of Verma. Finally, the Verma vector necessarily also does not include cPPT and CTS sequences “derived from a retrotransposon,” as recited by claim 41, and claims 42-46, 50, 51, and 62-65 as they depend from claim 41.

The Examiner cites the Charneau '92 and '94 references as disclosing the usefulness of cPPT and CTS sequences. However, those references do not teach use of those sequences in the context claimed by Applicant. Specifically, Applicant claims a “recombinant, non-replicative, non-infectious, lentiviral transfer vector.” The claimed vector comprises “non-infectious lentiviral nucleic acids, wherein the vector is deprived of functional genes encoding lentiviral Gag, Pol, and Env proteins.” In contrast, the Charneau references describe experiments with the cPPT and CTS in their native context, that is, in a context that is not deprived of functional genes encoding lentiviral Gag, Pol, and Env proteins. Nothing in the Charneau references suggest splicing the cPPT and CTS sequences into heterologous contexts.

Finally, while the level of skill in the molecular biology art is high, the state of the art at the time the invention was made was unpredictable. Certainly, without and until Applicant’s teachings, the skilled artisan would not have expected success in placing cPPT and CTS sequences into a vector as claimed by the inventors in order to transfer a defined nucleotide sequence into the nucleus of a cell.

The Facts Do Not Support a Conclusion of Obviousness

The Examiner states that the facts support the conclusion that the skilled artisan would have been motivated to combine the references to arrive at the claimed invention in order to "improve the replication of the viral vector inside a cell." However, as recited in the amended claims, the claimed transfer vectors are "non-replicative." Thus, a desire to create a vector having enhanced replication would in fact teach the skilled artisan away from the claimed invention.

Additionally, nothing in the references motivates creation of a vector that combines cPPT and CTS sequences with a vector that is "deprived of functional genes encoding lentiviral Gag, Pol, and Env proteins," as recited by the amended claims.

Finally, nothing in the cited reference discloses or suggests making a vector that uses cPPT and CTS sequences derived from a retrotransposon, as recited in claims 41-46, 50, 51, and 62-65.

For the above reasons, a rationale to support obviousness in view of the factual record is lacking. Accordingly, the rejection for obviousness should be withdrawn.

**E. Conclusion**

Further examination of this application and allowance of the claims at the Examiner's convenience are respectfully requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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